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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,266	05/14/2001	Naoki Kimura	06501-040002 / C1-806PCT-	9570

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EXAMINER
SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/855,266	KIMURA ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 28-40* is/are pending in the application.

4a) Of the above claim(s) *28-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/411,722* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This office action is response to Applicant's election of Group I, drawn to claims 1-8. Election was made with traverse in Paper No. 9 (10/17/02). The traversal is on the ground(s) that there would not be undue burden to search the sequences SEQ ID No: 1-3. The argument is persuasive. The Office will search the polypeptide sequences SEQ ID No: 1, 2 and the polypeptide encoded by SEQ ID NO:3.

Applicant is advised that a rejoinder of the claims of Groups I and III is possible at a later date if the product is eventually found patentable. Guidance on treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86.

To facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office Action may be made final, or, if the application was already under

DETAILED ACTION

1. This office action is response to Applicant's election of Group I, drawn to claims 1-8. Election was made with traverse in Paper No. 9 (10/17/02). The traversal is on the ground(s) that there would not be undue burden to search the sequences SEQ ID No: 1-3. The argument is persuasive. The Office will search the polypeptide sequences (SEQ ID No: 1 and 2) related to the instant invention.

Applicant is advised that a rejoinder of the claims of Groups I and III is possible at a later date if the product is eventually found patentable. Guidance on treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86.

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final rejection, the next Office Action may be an advisory action. Claims 28-40 are withdrawn from further consideration. Therefore, the restriction requirement is deemed proper and made FINAL. Claims 1-8, SEQ ID No: 1-3 are examined.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. Please update the priority information to include the allowed patent information.

Drawings

4. The draftsperson has objected to the drawings (see attached PTO 948).

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 1, 3, 9, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The specification discloses amino acid sequences of SEQ ID NO: 1 and 2 or amino acid encoded by SEQ ID No: 3. This meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the specification does not disclose amino acid sequences, which are at least 60%, 70%, 80% or 90% identical to the amino acid sequence of SEQ ID NO: 2 or a polypeptide that contains up to 30 conservative amino acid substitutions of SEQ ID No: 2 or a polypeptide encoded by a first nucleic acid that hybridizes under stringent conditions to a second nucleic acid consisting of SEQ ID No: 3. The claims as written, however, encompass nucleotide and amino acid sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claims 1-8. The specification does not provide written to support the genus encompassed by the instant claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (*See Vas-Cath* at page 1116).

With the exception of an isolated amino acids of SEQ ID No: 1 and 2 and amino acid encoded by SEQ ID NO: 3, the skilled artisan cannot envision all the detailed chemical structure of the claimed amino acid and nucleotide sequences, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only the isolated amino acid sequences of SEQ ID NO: 1 and 2 and amino acid encoded by sequence of SEQ ID NO: 3, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. As a result, it does not appear that the inventors were in possession of various polypeptide sequences set forth in claim 1-8.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent

Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

5b. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated amino acid sequences of SEQ ID NO: 1 and 2 or amino acid encoded by SEQ ID No: 3 does not reasonably provide enablement for amino acid sequences, which are at least 60%, 70%, 80% or 90% identical to the amino acid sequence of SEQ ID NO: 2 or a polypeptide that contains up to 30 conservative amino acid substitutions of SEQ ID No: 2 or a polypeptide encoded by a first nucleic acid that hybridizes under stringent conditions to a second nucleic acid consisting of SEQ ID No: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the

existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The instant claims read on amino acid sequences, which are at least 60%, 70%, 80% or 90% identical to the amino acid sequence of SEQ ID NO: 2 or a polypeptide that contains up to 30 conservative amino acid substitutions of SEQ ID No: 2 or a polypeptide encoded by a first nucleic acid that hybridizes under stringent conditions to a second nucleic acid consisting of SEQ ID No: 3. However, other than the isolated .amino acid sequences of SEQ ID NO: 1 and 2 or amino acid encoded by SEQ ID No: 3, the specification as filed fails to disclose any other polypeptide sequences.

Despite knowledge in the art for producing homologues of a given protein with nucleotide deletions, insertions or subtitutions the specification fails to provide any guidance regarding the changes/modifications contemplated and yet retain the function of the protein. Furthermore, detailed information regarding the structural and functional requirements of the disclosed protein is lacking. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (Wells 1990, Ngo et al., 1994). Although it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a protein's structure and function from mere sequence data remains an elusive task. Therefore, predicting which homologues would retain the

functions of the protein is well outside the realm of routine experimentation. Thus, undue amount of experimentation would be required to generate changes/modifications contemplated and yet retain the function of the proteins claimed.

Applicant has not taught how one of skill in the art would use the full scope of polypeptide sequences encompassed by the invention of claims 1-8. The specification as filed does not sufficiently teach one of skill in the art how to make and/or use the full scope of the claimed sequences. The amount of experimentation required to make and/or use the full scope of the claimed sequences would require trial and error experimentation to determine the functional sequences. Given the breadth of claims 1-8 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior at of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claim 8 recites " an isolated nucleic acid that hybridizes under stringent hybridization conditions .....", stringent conditions is a relative term and renders the claim indefinite. Furthermore, some nucleic acids which might hybridize under

conditions of moderate stringency, for example, would fail to hybridize at all under conditions of high stringency. The metes and bounds and bounds of the claim, thus cannot be ascertained. This rejection could be obviated by providing specific conditions supported by the specification which Applicants consider to be "stringent."

6b. Claim 7 recites "conservative substitution". However, "conservative substitution" is a relative recitation in that a number of properties could be conserved with amino acid substitution, including but not limited to amino acid structure of the amino acid being replaced, overall protein structure and protein function wherein function could be defined as immunogenicity, cell specificity, proliferative activity etc. Without knowing which property is the target of the conservation, the metes and bounds of a "conservative substitution" are unclear.

7. No claims are allowable but are apparently free of prior art.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph. D., whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JEFFREY STUCKER
PRIMARY EXAMINER

JS
December 18, 2002